

**Translation**

PATENT COOPERATION TREATY

PCT/JP2003/015576



**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03-074-PCT	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. PCT/JP2003/015576	International filing date (day/month/year) 05 December 2003 (05.12.2003)	Priority date (day/month/year) 05 December 2002 (05.12.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/216, 31/737, 31/78, 35/80, A61P 19/08, 19/10, 43/00 // C08B 37/00		
Applicant TAKARA BIO INC.		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 22 March 2004 (22.03.2004)	Date of completion of this report 09 July 2004 (09.07.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/015576

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/15576

## Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
  - ☐ restricted the claims.
  - ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
  - ☐ complied with.
  - ☒ not complied with for the following reasons:

Medical purposes themselves such as enhancing osteogenic protein production or promoting ontogenesis are merely publicly known. In view of this point, claims 1-11 include an invention of a medicine containing acidic saccharides, polyacrylic acid, chlorogenic acid, or alga-origin extract as the active ingredient. However, in this technical field, the above four ingredients do not belong to a group of compounds recognized as a group; nor do they have a common special technical feature. Therefore, this international application does not meet the requirement of unity of invention.

Also, there is no other matter that is common to all of the claims and is considered as a special technical matter; therefore, the number of inventions included in the present application is four.

4. Consequently, this report has been established in respect of the following parts of the international application:

☒ all parts.

☐ the parts relating to claims Nos. \_\_\_\_\_

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/15576

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims		YES
	Claims	1-11	NO
Inventive step (IS)	Claims		YES
	Claims	1-11	NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

## 2. Citations and explanations (Rule 70.7)

Document 1: JP, 7-109222, A (Maruha Corp.), April 25, 1995 (04.25.95)  
 Document 2: JP, 2002-226380, A (Maruho K.K.), August 14, 2002 (08.14.02)  
 Document 3: JP, 6-22728, A (Asahi Chemical Industry Co., Ltd.), February 1, 1994 (02.01.94)  
 Document 4: JP, 10-53531, A (Hoechst AG.), February 24, 1998 (02.24.98)  
 Document 5: JP, 3-287538, A (Sunstar Inc.), December 18, 1991 (12.18.91)  
 Document 6: JP, 7-101871, A (Lion Corporation), April 18, 1995 (04.18.95)  
 Document 7: JP, 11-502235, A (Gutierrez, Gilles), February 23, 1999 (02.23.99)  
 Document 8: 2000-344672, A (Meiji Milk Products Co., Ltd.), December 12, 2000 (12.12.00)  
 Document 9: WO, 01/076580, A1 (Takara Bio K.K.), October 18, 2001 (10.18.01)

[1] The inventions described in claims 1-11 do not appear to be novel based on documents 1-7 cited in the ISR.

Document 1 describes that a chondroitin sulfate sodium salt is useful for bone reinforcement and osteoporosis.

Thus, the inventions described in claims 1-9 of the present application do not appear to be novel.

Document 2 describes that a sulfated saccharide is useful for matrix metalloprotease-related diseases, and the related diseases are chondropathy and other various diseases.

Thus, the inventions described in claims 1-9 of the present application do not appear to be novel.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/15576

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 02/098449 A1 [E X]	12.12.2002	03.06.2002	01.06.2001
JP 2003-26597, A [E X]	29.01.2003	11.07.2001	
JP 2004-2375 A [E X]	08.01.2004	09.04. 2003	10.04.2002

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.  
Continuation of Box V:

Document 3 describes that pectate calcium has an effect of reinforcing bones; therefore, the inventions described in claims 1-9 of the present application do not appear to be novel.

Document 4 (claim 7) describes that a polyacrylic acid is useful for a rheumatic condition; therefore, the inventions described in claims 1-9 of the present application do not appear to be novel.

Document 5 describes that a polyacrylic acid is useful for reproducing and promoting periodontal tissues; therefore, the inventions described in claims 1-9 of the present application do not appear to be novel.

Document 6 describes that various seaweed extracts are useful as an arthrosis remedy; therefore, the inventions described in claims 10 and 11 of the present application do not appear to be novel.

Document 7 describes that a Dictyotales-origin extract is useful for remedy of tissue damage of bones and cartilages, and the extract can be obtained from brown algae and the like. Thus, the inventions described in claims 10 and 11 of the present application do not appear to be novel.

[2] The inventions described in claims 1-9 do not appear to involve an inventive step based on documents 8-9 cited in the ISR.

Document 8 describes that a tannin compound is useful for intractable diseases caused by a matrix metalloprotease activity control inability, and the diseases are osteoarthritis, bone disease and the like.

Document 8 does not disclose a chlorogenic acid. However, in addition, document 9 describes that a caffeic acid identical to a chlorogenic acid in a chemical structure is useful as a cartilage protective agent.

Thus, applying a chlorogenic acid which is a tannin compound to osteoarthritis, bone disease and the like could be easily conceived of by a party skilled in the art.